REMARKS/ARGUMENT

Claim Rejection - 35 U.S.C. §101.

The claim must be for a practical application, which can be identified: (i) by the invention transforming an article to a different state or thing, or (ii) by the invention otherwise producing a useful, concrete, and tangible result. Interim Guidelines for Examination of Patent Applications for Patent Subject Matter, U.S.P.T.O., OG Notices 22 November 2005, at http://www.uspto.gov/web/offices/com/sol/og/2005/week47/patgu.pa.htm (hereinafter, "Guidelines"). The present Invention's configuration or scheduled steps for analyzing a set of declarative statements leaves the abstract domain and enter the concrete world of the artificial domain when the analysis is recorded. Although many of the recited steps themselves involve manipulation of abstract ideas they are affected by an artificial (man-made) agency, thereby making the subject matter statutory. Claims 1 and 2 of the Invention, as amended, recite several recording steps that result in creation of an artificial entity - a Pain Index Score, and a probability equation score, which did not exist before in the artificial world. The agency responsible for effecting this change is having the steps of: (1) recording the patient attribute responses to the declarative statements on the response sheets, (2) scoring the responses on the validity and clinical factor sheets, and (3) providing for a recordable Pain Index Score and a Probability Equation Score set down on the Paindex® outcome analysis, thereby creating a predictable and repeatable artificial, assessment score. Specification, pp. 11-13 and Figs. 2-12.

The present invention as fully described by the Applicant is an advancement and improvement over his prior methodology in this art, as set forth in the Specification, and as such, a

more predictable method over what was already considered by those with ordinary skill in the art, to have a high level of predictability. Specification, p. 2, *citing*, Charles Hamlin, Michael Hitchcock, John Hofmeister, and Robert Owens, "Predicting Surgical Outcome for Pain and Relief and Return to Work," Best Practices and Benchmarking Healthcare, Mosby-Year Book, Inc., Vol. 1, No. 5 (Sept./Oct. 1996), St. Louis, pp. 258-261 (hereinafter, "Hamlin et al, 1996 ").

Therefore, Applicant respectfully submits that the Office Action fails in its initial burden to present a prima facie case of unpatentability. Guidelines, p. 11, *citing, In re Oetiker*, 977 F.2d 1443,1445, 24 U.S.P.Q. 2d 1443, 1444 (Fed Cir. 1992). Given the support provided by those with ordinary skill in the art by Hamlin et al 1996, and by the fact that the Inventor has strived to invent a method that improves on the level of predictability in the previous work, the record as a whole suggests that it is more likely than not that the present invention is a practical application of an abstract idea, and the Office Action should not have rejected the Claims. Therefore, the Office Action should have given Applicant's Claims their broadest reasonable interpretation in light of the supporting disclosure. Guidelines, p. 3, *citing, In re Morris*, 127 F.3d 1048, 1054-55, 44 U.S.P.Q. 2d 1023, 1027-28 (Fed Cir. 1997). While maintaining this argument, and that Claims as set forth in the Application provided a tangible result eligible for patent protection, the Applicant has amended his Claims hereby ands is making a showing of why these claims are eligible for patent protection. Guidelines, p. 11. MPEP § 2107.

When an abstract idea is reduced to a practical application, the abstract idea no longer stands alone if the practical application of the abstract idea produces certain useful, concrete, and tangible results, thus satisfying the requirements of 35 U.S.C. §101. *In re: Alappat*, 31 U.S.P.Q. 2d 1545,

1558 (Fed. Circ. 1994); *State Bank & Trust Co. v. Signature, Inc.*, 149 F. 3d 1368, 1373, 47 U.S.P.Q. 2d 1596, 1601 (Fed. Cir. 1998), *cert. denied*, 525 U.S. 1093 (1999). For example, a predictive model may be used to optimize return on marketing investment by ranking consumers according to their predicted response to promotions, and then mailing promotional materials only to those consumers who are most likely to respond and generate revenue. *Ex parte Edwin Peter Dawson Pednault*, Appeal No. 2002-0308 (BPAI), *unpubl'd. op.* As set forth below, the Hamlin Declaration provides evidence confirming this facts, providing a useful, concrete, and tangible result.

A. Useful Result

To be useful, the utility of an invention must be (i) specific, (ii) substantial, and (iii) credible. Guidelines, p.9. The Office Action states that the Invention appears to be specific, substantial, and credible. Office Action, p.2. Applicant asserts that this is indeed the case. The Claims set forth that (1) they produce a single pain index score indicating and measuring the effect of somatization on the patient, and (2) they produce an outcome analysis graph diagnosing the probability of pain relief through medical treatment in the patient.

Applicant respectfully submits that Claims 1 and 2 are supported by either a specific and substantial asserted utility or a well-established utility, for the reasons set forth. Particularly with respect to the assertions by the Hamlin, et al 1996, article regarding the related art, and by his recent analysis, *see* Hamlin Declaration, para. 16, it is readily apparent that the claimed invention has a well-established, practical utility, with immediate benefit to the public, rebutting the basis or logic of the argument of no specific and substantial credible utility under 35 U.S.C. §101 and §112.

B. **Tangible Result**

The "tangible" element requires that the claim must set forth a practical application to produce a real-world result, guidelines, p. 10.

Claims 1 and 2 of the Invention recite a method of diagnostic test or system for identifying and quantifying certain psychological and behavioral, or clinical, factors having a critical bearing on decisions by physicians for medical treatment of patients and predicting patient problems that can occur post-operatively due to somatization. The method transforms scores representing psychological/psychiatric assessments, into a final, repeatable score using a computational model of a series of mathematical calculations or data set.

The analysis in the Hamlin Declaration assesses the Invention as a repeatable method with a highly beneficial practical application. Hamlin Declaration, para. 11 and 13. As set forth herein, the Claims produce a physical transformation of the subject matter. The computational model is programmed to transform the data, which represents discrete personality scores, into a final recordable score, constituting a practical application of mathematical algorithms, formulae, or calculations producing "a useful, concrete, and tangible result," i.e., the final pain index score upon which physicians can make medical, treatment decisions. Specification, pp. 1-5. *See State Street,* 149 F. 3d at 1374,-75. Transformation and reduction of an article to a different state or thing is the clue to patentability of a process or method Claim that does not include a particular machine. Guidelines, p. 15, *citing*, *Diamond v. Diehr*, 450 U.S. 175, 188-189, 209 U.S.P.Q. 1,9 (1981).

C. **Concrete Result**

The method must have a result that can be substantially repeatable, or substantially produce

the same result again. Guidelines, p. 10. Dr. Charles Hamlin has employed Dr. Smith's Invention and analyzed the Invention as to its predictability. Hamlin Declaration, para. 11 and 13. Dr. Hamlin found the Invention to be highly predictable and substantially repeatable. *Id* at para. 14 and 15.

Claim Rejections - 35 U.S.C. § 112

The Applicant respectfully traverses the argument set forth in the Office Action that the invention is not supported by specific or substantial utility or well established utility so that one skilled in the art would not know how to use the invention without undue experimentation because the invention lacks substantial repeatability, for the reasons set forth elsewhere in this Response and as follows:

As set forth in the Specification, the present Invention specifically identifies and quantifies psychological problems and predicts, to a high statistical probability (i.e., demonstrating a substantial and credible utility and repeatability), the probability of patient pain relief, where symptoms do not correspond with diagnostic studies and/or physical symptoms. Hamlin, et al 1996, at p. 258. A person of ordinary skill in the art would immediately appreciate why the Invention is useful based on the characteristics of the Invention, the properties and applications of the Applicant's method, as set forth. MPEP §2107.

The enablement concerns set forth in the Office Action stem from doubts as to whether the invention is capable of substantial repeatability. However, the Applicant's Specification clearly does not lend credence to such doubts. In calling the enablement of disclosure into question, an Office Action has the burden of advancing acceptable reasoning inconsistent with enablement. *In*

re Strahilevitz, 668 F.2d 1229, 1232, 212 U.S.P.Q. 561, 563-64 (CCPA 1982). This substantial repeatability is confirmed by the recent analysis of Dr. Charles Hamlin. Hamlin Declaration, para. 11 through 15. In view of the disclosure in Applicant's Specification, as well as the support provided by the Hamlin Declaration, the Applicant has established that the invention will function in the manner disclosed and claimed.

Responses to Arguments under 35 U.S.C. §101 & 112

In the response to Applicant's arguments filed November 16, 2005, the Office Action rejects certain arguments of the Applicant, as set forth beginning on page 4. Applicant respectfully traverses the response in the Office Action to overcome the 38 U.S.C. § 101 and 112 rejections, as follows:

A. With regard to Applicant's assertion that the invention leaves the public domain and enters the concrete world of the artificial domain when the analysis is recorded, the Office Action argues that the claims do not state that the analysis is ever recorded, that the claims never recite a recording step and never recite anything being written down or recorded..

In page 2, lines 6-9, of the Specification, the Applicant provides for such recording by setting forth the general quantifying and recording elements of the Invention, stating that the present invention identifies and quantifies psychological problems. The Specification further states, in pages 4, lines 6-7, and 5, lines 20-23, that the Invention utilizes declarative statements from the MMPI in a test given to the patient, the MMPI being a widely used, standardized written test for the diagnosis of psychopathology and personality attitudes and characteristics well known in the industry. Page 7, Fig. 2, of the Specification, states that a response sheet is used to record patient

responses to the declarative statements and subsequent scoring values.

Once the test containing the declarative statements is completed, the nine scoring templates are applied for tabulation and evaluation of the patient's responses, as set forth in Specification, Page 11, lines 14-16. Raw scores for each of the validity and clinical factors are recorded on the response sheet. Specification Fig. 2, and Page 12, lines 23-25; Page 13, line 5; Page 14, lines 5, 11-12; Page 16, lines 9-10; and Page 17, lines 22-24. As set forth in Pages 18 and19, lines 22-25 and 1-2, respectively, the raw scores, the adjustment scores, and the resultant final scores are all recorded on the response sheet, Fig. 2. Such scores are adjusted to mean *t* scores, or deviation scoring values, to determine relative deviation and interpretative importance, which are tabulated and recorded on the response sheet, Fig. 2, as set forth in Pages 21, 22, and 23, lines 11-14 and 23-25, 10-12 and 17-21, and 2-5, respectively. The summation of all of the *t* scores, the Pain Index Score, is recorded on the response sheet, Fig. 2. *See also,* the Hamlin Declaration for a brief review of the administration of the Invention.

Applicant has made the following amendments in response to the allegation of lack of such recording in the claims:

Applicant has overcome said rejection of Claim 1 by amending and rewriting independent Claim 1, providing for separate method steps starting with the word *"recording"* and thereby recording the analysis as set forth in the Specification.

Claim 1 (c) - (u), pages 2-4 of the Applicant's response filed on November 16, 2005, and previously presented, are re-lettered respectively to reflect claim 1 as amended by this response to provide for said separate method steps.

B. With regard to Applicant's assertion that the subject matter is statutory because the abstract ideas are affected by an artificial agency, the Office Action argues that such manipulation does not make statutory subject matter. The Applicant respectfully refutes and traverses this assertion in the Office Action as follows:

Claim 1, as amended hereby, recites several recording steps that result in the creation of an artificial entity - a pain index score, as a predictor of somatization. The process of writing down and establishing the pain index score, itself, affects a change in the artificial world because now something exists in the artificial world that did not exist before. The agency responsible for affecting this change is the act of recording the various scores on the scoring sheets. Specification, pp. 11-13, Figs. 2-12, and amended Claim 1 above. The Pain Index Score, an artificial element, gave substance to the responses of the patient as statutory subject matter. Gregory A. Stobbs, Business Method Patents, Aspen Publishers, Inc. (2002), p. 63, 65-66 (analyzing method patent U.S. Patent # 5,278,750 to Toyota Motor Company, for making a production schedule, reciting several recording steps, creating an artificial entity - a written shipment schedule).

Therefore, the methods employing abstract ideas to perform a real-world function are, when the claim is considered as a whole, as a particular application of abstract ideas, in this case as an important predictor of somatization, rather than for the abstract idea itself. Guidelines.

C. With regard to the arguments of the Office Action that: (i) patient responses were in the abstract domain, (ii) the Paindex ® outcome analysis is not claimed, (iii) and the Pain Index Score fails to produce a useful, concrete and tangible result; the Applicant respectively states as follows:

(i) With regard to the patient responses, Claim 1 has been amended as ser forth in Section A above, on page 13-14.

(ii) With regard to claiming Paindex ® Outcome Analysis, Fig. 15 and Page 23, lines 4-19, of the specification, the Applicant provides in the Specification for the Paindex ® outcome analysis as a plot of two independently determined outcome predictive values, the Pain Index Score determined from certain recorded patient responses and scoring values claimed in the Invention and the Probability Equation Score determined from other certain recorded patient responses and the O predictiveness validity factor claimed in the Invention, as set forth in the Specification, Pages 5-6, lines 20-23 and 1-8, respectively, and Page 9, lines 9-13. The Paindex ® Outcome Analysis graph is a plot of the two outcome predictive values, setting forth a comparative analysis, diagnosing the probability of pain relief in the patient, as set forth in Fig. 15 and Page 23.

Applicant made the following amendment, to better reflect the intended scope of the Claim 2, in response to the Office Action argument of not claiming the Paindex ® Outcome Analysis:

Applicant has overcome said rejection by amending and rewriting Claim 2, providing for and claiming the outcome analysis graph diagnosing the probability of pain.

(iii) With regard to producing a "useful, concrete and tangible result", Applicant incorporates the arguments set forth above and asserts, additionally, as follows:

. As set forth in *State Bank, supra*; the transformation of data through a series of mathematical calculations (in that case, into a final share price), constitutes a practical application of a mathematical algorithm or calculation, because it produces a "useful, concrete and tangible result," that being "a final share price momentarily fixed for recording and reporting purposes and

even accepted and relied upon by regulatory authorities and in subsequent trades." As pointed out in *State Street Bank*, transformation of data is enough to constitute a practical application. *Id.* at 15-16. Therefore, to be "useful, concrete and tangible" the Invention must possess a certain level of "real world" value, Guidelines, p. 2.

Applicant's Invention is a practical method and means of providing a highly beneficial, medical result. Guidelines, p. 8. The Applicant sets forth in the Specification, Page 1, indication of the Invention - "a self-reporting diagnostic test that identifies and quantifies certain psychological and behavioral, or clinical factors" that "can affect medical treatment outcome for a patient sensitive to somatization" and thereby "have a critical bearing on a decision by a physician to operate or otherwise medically treat a patient, on predicting problems that could occur post - operatively or after treatment." This statement by Applicant clearly sets forth immediately to one ordinarily skilled in the art why the Applicant believes the Invention is useful, Guidelines, p. 2. As confirmed in the Office Action, p. 2, the "claimed invention appears to the examiner to be specific and substantial, and credible." MPEP §2107. As a result, the Invention's transformation of data through a series of mathematical calculations (to a single Pain Index Score, and to a Probability Equation Score indicating and measuring the effect of somatization on a patient), constitutes a practical application of a mathematical algorithm or calculation. Dr. Charles Hamlin confirms this fact. Hamlin Declaration, para. 9,12,14, and 16.

D. The Office Action agrees with the Applicant's assertion that the Invention does not claim the underlying mathematical algorithms. However, as set forth above, the transformation of data by the Invention through a series of mathematical calculations (in this case, into a Pain Index

Score), constitutes a practical application of a mathematical algorithm or calculation.

E. With regard to the arguments of the Office Action that the method of diagnosing a probability of pain relief does not produce substantially repeatable, or "concrete" results, the Applicant respectfully submits the following:

Applicant submits that concreteness is met by the Invention for the reasons already stated above and in view of evidence in support thereof from the Hamlin Declaration attached hereto, providing evidence demonstrating the assertions and conclusions made by the Applicant. As actual evidence proving the assertions and conclusions made by the Applicant, Dr. Charles Hamlin confirms that the configuration by the Invention's patient response analysis into certain validity factor scales and clinical factor scales in the Claims, specifying the recorded attributes of the patients from responses to the MMPI, affect a patentable subject matter as a change in the natural world because patients' attitudes are not naturally configured or arranged in this manner in the natural world, and are, therefore, concrete. Hamlin Declaration, para. 9 through 12. The analysis in the Hamlin Declaration assesses the Invention as a repeatable method with a highly beneficial, practical application. Hamlin Declaration, para. 15 and 16.

SPECIFICATION:

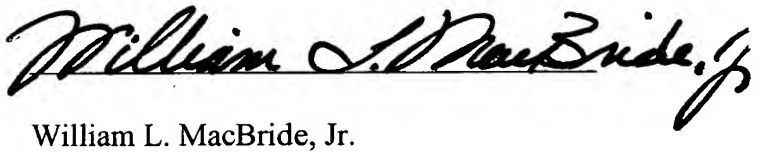
Applicant has amended the Specification, on Page 23, line 5, to correct a typographical error, deleting the number "~~304~~" and inserting the number "204".

CONCLUSION

For all the reasons advanced above, the Applicant respectfully submits that a timely Notice of Allowance be issued in this case.

Respectfully submitted,

WILLIAM L. MACBRIDE, JR.
Attorney for Applicant



William L. MacBride, Jr.
Reg. No. 46,891

Gough Shanahan, Johnson & Waterman
33 South Last Chance Gulch
P.O. Box 1715
Helena, MT 59624-1715
(406) 442-8560